

## Demonstrated Safety Profile

### Blood Parameters<sup>3,5</sup>

In clinical trials for KYZATREX, patients experienced the following changes in average blood parameters at 6 months.

Prostate-Specific Antigen (PSA)	↑ 0.15 (±0.04) ng/mL
Hemoglobin	↑ 0.48 g/dL Levels plateaued after 90 days of treatment
Total Cholesterol	↓ 11.1 mg/dL
Triglycerides	↓ 18.6 mg/dL
Fasting Insulin <sup>†</sup>	↓ 5.2 µu/mL

<sup>†</sup>Data from MRS-TU-2019 (n=153) at 12 months. Fasting insulin was an exploratory endpoint; this study was not designed or statistically powered to demonstrate differences in exploratory endpoints. MRS-TU-2019 had a different dosing scheme from MRS-TU-2019EXT.

### Side Effects in Clinical Trials

- The most common side effect reported with KYZATREX is an increase in blood pressure, observed in 2.6% of patients.
- One patient discontinued because of an adverse reaction (acne).
- No patients discontinued due to erythrocytosis.

The most common side effect of KYZATREX is high blood pressure. Other side effects may include: headache, joint or back pain, diarrhea, increased red blood cell count, anxiety, constipation, swelling of the legs, and increased prostate specific antigen (PSA) levels.

Please see additional Important Safety Information on the back.

## Ask Your Doctor if KYZATREX is Right for You

To learn more about KYZATREX, visit [www.kyzatrex.com](http://www.kyzatrex.com) or scan the QR code.



If you already have an enlarged prostate, your signs and symptoms may worsen while taking KYZATREX. These may include: increased urination at night; trouble starting your urine stream; urinating many times during the day; urge to go to the bathroom right away; a urine accident; inability to pass urine or weak urine flow.

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Actor Portrayal

## Start Taking Control of Your Health Today!

KYZATREX is an oral testosterone treatment designed to fit effortlessly into your life.

### Easy to Take

Just take two KYZATREX doses a day with food. No needles, pellets, patches, or gels.

### Bypasses the Liver

By bypassing the liver altogether, KYZATREX helps avoid the liver toxicity often associated with previous generations of oral testosterone.<sup>3</sup>

### Flexible Dosing

Your dose can be adjusted based on how your body responds to KYZATREX.

### See the Difference

	KYZATREX <sup>®</sup>	Injections	Pellets	Gels
Oral Capsule	✓	✗	✗	✗
Discreet	✓	✓	✓	✓
No Mess	✓	✓	✓	✗
Painless	✓	✗	✗	✓
Flexible Dosing	✓	✓	✓	✓

KYZATREX may cause serious side effects, including liver problems. Symptoms of liver problems may include: nausea or vomiting; yellowing of your skin or whites of your eyes; dark urine; pain on the right side of your stomach area (abdominal pain).

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### What is KYZATREX<sup>®</sup>

KYZATREX<sup>®</sup> (testosterone undecanoate) is a prescription drug that is used to treat adult men who have low or no testosterone levels due to certain medical conditions.

KYZATREX<sup>®</sup> is a controlled substance (CIII) because it contains testosterone.

It is not known if KYZATREX<sup>®</sup> is safe or effective in males younger than 18 years old. Improper use may affect bone growth in children.

It is not known if KYZATREX<sup>®</sup> is safe or effective in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”).

KYZATREX<sup>®</sup> is not meant for use by women.

#### Important Safety Information for KYZATREX<sup>®</sup>

**Do not take KYZATREX<sup>®</sup> if you:** have breast cancer; have or might have prostate cancer; are a woman who is pregnant (KYZATREX<sup>®</sup> may harm your unborn baby); or are allergic to KYZATREX<sup>®</sup> or any of its ingredients.

**Before you take KYZATREX<sup>®</sup>, tell your healthcare provider about all of your medical conditions, including if you:** have high blood pressure or are treated for high blood pressure; have a history of diabetes; have heart problems; have high red blood cell count (hematocrit) or high hemoglobin laboratory value; have urinary problems due to an enlarged prostate; have liver or kidney problems; or have problems breathing while you sleep (sleep apnea).

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.** Taking KYZATREX<sup>®</sup> with certain other medicines can affect each other. **Especially, tell your healthcare provider if you take:** insulin; medicines that decrease blood clotting (blood thinners); corticosteroids; or medicines that increase blood pressure, such as some cold medicine and pain medicines.

**KYZATREX<sup>®</sup> may cause other serious side effects including:**

- **Increase in red blood cell count (hematocrit) or hemoglobin,** which can increase the risk of blood clots, strokes, and heart attacks. You may need to stop KYZATREX<sup>®</sup> if your red blood cell count increases.
- **If you already have an enlarged prostate, your signs and symptoms may worsen while taking KYZATREX<sup>®</sup>.** These may include: increased urination at night; trouble starting your urine stream; urinating many times during the day; urge to go to the bathroom right away; a urine accident; inability to pass urine or weak urine flow.
- **Increased risk of prostate cancer.**
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Abuse.** Testosterone can be abused when taken at higher than prescribed doses and when used with

other anabolic androgenic steroids. Abuse can cause serious heart and psychological side effects.

- **In large doses, KYZATREX<sup>®</sup> may lower your sperm count.**
- **Liver problems.** Symptoms of liver problems may include: nausea or vomiting; yellowing of your skin or whites of your eyes; dark urine; pain on the right side of your stomach area (abdominal pain).
- **Swelling of your ankles, feet, or body (edema), with or without heart failure.**
- **Enlarged or painful breasts.**
- **Breathing problems while you sleep (sleep apnea).**

**Call your healthcare provider right away if you have any of the serious side effects listed above.**

**The most common side effect of KYZATREX<sup>®</sup> is high blood pressure.** Other side effects may include: headache, joint or back pain, diarrhea, increased red blood cell count, anxiety, constipation, swelling of the legs, and increased prostate specific antigen (PSA) levels.

These are not all the possible side effects of KYZATREX<sup>®</sup>. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You may also report side effects to Marius by visiting [www.mariuspharma.com](http://www.mariuspharma.com).

**Keep KYZATREX<sup>®</sup> and all medicines out of the reach of children.**

**See Full Prescribing Information and Medication Guide for KYZATREX<sup>®</sup> at [www.kyzatrex.com](http://www.kyzatrex.com).**

#### References:

1. Li Y, Liu M, Cui Y, et al. Increased risk of testosterone deficiency is associated with the systemic immune-inflammation index: a population-based cohort study. *Front. Endocrinol.* 13:975773. doi: 10.3389/fendo.2022.974773
2. National Population by Characteristics: 2020–2022. Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States: April 1, 2020 to July 1, 2022 (NC-EST2022-SYAEXN). U.S. Census Bureau. <https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html>. Accessed 8/11/23.
3. Bernstein JS, Dhingra OP. A phase III, single-arm, 6-month trial of a wide-dose range oral testosterone undecanoate product. *Ther Adv Urol.* 2024;16:1–17. doi: 10.177/17562872241241864
4. Krakowsky Y, Grober E. Testosterone deficiency – Establishing a Biochemical Diagnosis. *EJIFCC.* 2015 Mar; 26(2): 105–113.PMID: 27683486; PMCID: PMC4975356.
5. Data on file. Raleigh, NC: Marius Pharmaceuticals, 2020.
6. Data on file. Raleigh, NC: Marius Pharmaceuticals, 2018.



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@ TESTOSTERONE UNDECANOATE CAPSULES

## Restore Testosterone Levels With FDA-approved KYZATREX<sup>®</sup>



No Administration Pain



No Mess



No Transference Risk

KYZATREX is a prescription oral testosterone treatment for adult men who have low or no testosterone levels due to certain medical conditions. KYZATREX is a controlled substance (CIII) because it contains testosterone. It is not known if KYZATREX is safe or effective in males younger than 18 years old. Improper use may affect bone growth in children. It is not known if KYZATREX is safe or effective in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”). KYZATREX is not meant for use by women.

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Actor Portrayal


You're Not Alone


# Testosterone Deficiency is a Chronic Disease™


Low T Affects an Estimated **20 Million Men** from Ages 20–65 in the U.S.<sup>1,2</sup>


## Do These Symptoms of Low Testosterone Sound Familiar?


- 


Fatigue or low energy
- 


Trouble sleeping
- 

Low sex drive
- 

Loss of muscle mass
- 

Decreased bone density
- 

Depression
- 

Weight gain
- 

Anxiety

## Treatment Options for Low Testosterone

There are several forms of testosterone replacement therapy (TRT) available, including oral capsules, injections, pellets, and gels.

Oral TRT is the only option that combines needle-free administration, a painless experience, and the convenience of twice-daily oral dosing.

Do not take KYZATREX if you: have breast cancer; have or might have prostate cancer; are a woman who is pregnant (KYZATREX may harm your unborn baby); or are allergic to KYZATREX or any of its ingredients.

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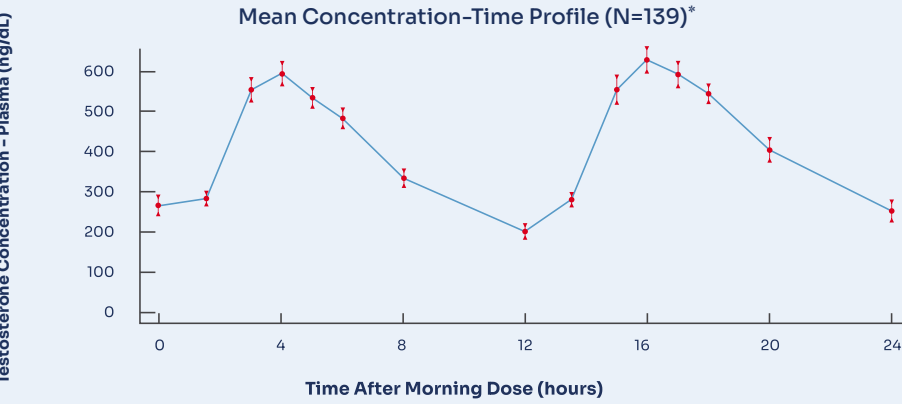
## Works with Your Body to Bring Testosterone Back into Balance

With a twice-daily dosing schedule, KYZATREX:

- ✔ Raises testosterone levels each time you take it (2 times per day). After each dose, your testosterone levels slowly decline before your next dose.
- ✔ Focuses on maintaining your testosterone within a range that is considered medically normal.
- ✔ Won't cause unnatural highs or extreme lows in your testosterone levels.
- ✔ Can raise your testosterone levels while maintaining your own testosterone production.

### A Dependable Rhythm of Testosterone Support

KYZATREX delivers reliable testosterone support between doses, maintaining balance without extreme highs and lows.



\*Mean (Standard Error of the Mean) Testosterone Concentration (ng/dL) Post Morning KYZATREX Dose at Day 90

Before you take KYZATREX, tell your healthcare provider about all of your medical conditions, including if you: have high blood pressure; have a history of diabetes; have heart problems; have high red blood cell count (hematocrit) or high hemoglobin laboratory value; have urinary problems due to an enlarged prostate; have liver or kidney problems; or have problems breathing while you sleep (sleep apnea).

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## Clinically Restore Testosterone Levels

Clinical Trial Results At Day 90:



Up to 96% Effective<sup>3\*</sup>

\*In a six-month clinical trial of 139 men with low testosterone, 88% of patients had normal testosterone levels at Day 90 (worst-case scenario calculation, excluding Investigator Site 104). Based on patients who completed the study (n=127), 96% of patients achieved normal testosterone levels at Day 90.



Free Testosterone Doubled<sup>3</sup>

This is the bioavailable form of testosterone that exerts the greatest androgenic activity in the body.<sup>4</sup>



30% Decrease in SHBG Levels<sup>5</sup>

SHBG can lock up testosterone, making it unavailable to your cells. Decreasing SHBG frees up more testosterone to do its job.<sup>4</sup>

KYZATREX may cause serious side effects, including an increase in red blood cell count (hematocrit) or hemoglobin, which can increase the risk of blood clots, strokes, and heart attacks. You may need to stop KYZATREX if your red blood cell count increases.

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## Are You a Candidate for KYZATREX?

You may be a candidate if your doctor has diagnosed you with low or no testosterone levels due to certain medical conditions. In particular, KYZATREX might be good for you if you meet the diagnosis criteria and:

- This is your first time pursuing testosterone replacement therapy.
- You prefer not to use needles.
- You are worried about transferring gel medication to loved ones.
- You are an existing TRT patient who is tired of having to donate blood due to high levels of hematocrit.\*

\*If you have previously experienced high hematocrit on testosterone replacement therapy, your doctor should continue to monitor your blood pressure and blood levels while you're on KYZATREX. If your hematocrit levels remain high, you may still need to donate blood to bring them down.

## What to Expect When Starting Treatment With KYZATREX

- ✔ KYZATREX is an immediate-release formulation. Testosterone levels begin to normalize following the first dose.
- ✔ If you're used to treatments like injections, you may notice that KYZATREX doesn't cause you to feel huge spikes in energy and performance. That's because KYZATREX maintains natural, dependable testosterone levels throughout the day and night.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking KYZATREX with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take: insulin; medicines that decrease blood clotting (blood thinners); corticosteroids; or medicines that increase blood pressure, such as some cold medicine and pain medicines.

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## Provider and Patient Preference for Oral Testosterone<sup>6</sup>

89%

of HCPs somewhat or strongly prefer KYZATREX to injectables\*

76%

of current TRT users said they would likely switch to an oral option if provided\*\*

\*2018 quantitative study of 78 Primary Care Physicians, Endocrinologists and Urologists  
\*\*2018 quantitative study of 83 hypogonadal patients; TRT users (n=49), Non-TRT users (n=34)

## Patient Testimonials

"I have recently taken my health into my own hands after my labs reflected low testosterone. I have been on KYZATREX for more than 4 months now and my testosterone levels are back to normal. My life has changed for the better. I really do attribute this jumpstart in health to KYZATREX."

Bryan N, 56

"For years, I used testosterone injections but wanted to switch to an oral TRT. My doctor recommended KYZATREX due to its tolerability and side effect profile and I've now been on KYZATREX for 8 months. My testosterone levels are about 700 ng/dL and I feel just as good, if not better, on KYZATREX than I did on injections."

Brian R, 47

"When I first discovered I had Low T, I went with pellet therapy. While pellets seemed fine at first, they eventually became too much of a hassle – the painful implant process, scar tissue buildup and activity restrictions just weren't for me, especially when the effects started wearing off before the next dose. As soon as I heard there was an oral option, that's when I switched to KYZATREX. I love the convenience of the capsules, and my testosterone levels are in the normal range! It's made a real difference in how I feel."

David W, 41

Testosterone can be abused when taken at higher than prescribed doses and when used with other anabolic androgenic steroids. Abuse can cause serious heart and psychological side effects.

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